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| 10/768,629  | 01/29/2004  | Karla Weaver         | 10123/00901                  | 6763                   |
| 7590 07/29/2008   |             |                      |                              |                        |
| Patrick J. Fay, Esq.<br>FAY KAPLUN & MARCIN, LLP<br>Suite 702<br>150 Broadway<br>New York, NY 10038 |             |                      | EXAMINER<br>WACHTEL, EMILY L |                        |
|   |             |                      | ART UNIT<br>3767             | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/768,629

**Applicant(s)**

WEAVER ET AL.

**Examiner**

EMILY WACHTEL

**Art Unit**

3767

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Prosecution has been reopened to include the following objections and rejections under 35 USC 112. The 35 USC 103 rejections are maintained with the original art of record as set forth in the final office action mailed March 17, 2008.

#### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the mounting portion must be explicitly shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Based on the specification it is unclear exactly what portion of the device, especially in accordance with the drawings, constitutes the recited mounting portion.

***Claim Objections***

3. Claim 2 is objected to because of the following informalities: Claim 2 recites "...an annular base member wherein an area of the base membrane...". It is unclear if the recited base membrane is the same as the annular base member. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The mounting portion which covers a minority of the surface area of the lumen occluding portion in which the slit is disclosed as recited in the claims contains matter new to the application. Nowhere does the specification relate that the mounting portion covers a minority of the surface area of the lumen occluding portion. Further, based on Figure 4, which was cited

as support for the amendment, it is unclear which portion is the mounting portion and there is no concrete support that any apparent mounting portion only covers a minority of the surface area of the lumen occluding portion.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "...the thickness of the mounting portion is greater than a thickness of the lumen occluding portion..." is unclear. The claim previously states that the mounting portion is part of the flow control membrane. According to the specification, with references to the drawings member 102 is the flow control membrane. It is initially indefinite exactly which portion of the device is the recited mounting portion. Further, it is indefinite as to if the thickness of the mounting portion is greater than a thickness of the lumen occluding portion regarding membrane 102 alone or when combined with membrane 104, and in the instance when the two are combined, again, it is unclear specifically which portion of the device is the mounting portion. For purposes of examination, the mounting portion is taken to be that generally indicated by reference numeral 108 in the drawings and further that it is the overall thickness of the mounting portion when membranes 102 and 104 are combined that has a thickness greater than the lumen occluding portion. Additionally, the term minority has not been sufficiently defined. For purposes of examination, the term minority is taken to mean less than fifty percent.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) in view of Ohringer (U.S. Patent 3,811,466).

With regards to claim 1, Moorehead et al. teach a pressure activated slit for medical applications (Col. 2 line 10) comprising a housing having a lumen extending therethrough from a proximal end to a distal end (Fig. 2 element 42), a flow control membrane (Fig. 5 elements 120, 124) including a mounting portion at which the flow control membrane is coupled to the housing (Fig. 5 element 120, Col. 6 lines 1-5) and a lumen occluding portion having a slit (Fig. 5 element 124, 146) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Col. 2 lines 29-32) and wherein a thickness of the mounting portion is greater than a thickness of the lumen occluding portion (Fig. 5 elements 120, 124, Col. 7 lines 17-20 base members add thickness to the mounting portion and not to the area encompassing the slit). Moorhead et al. further teach that the length of the slit is a variable set based on the desired pressure differential (Col. 7 lines 22-25 and 30-35) and that the size of the apertures in the discs surrounding the element are also variable and set based on the desired pressure differential required to open the slit (Col. 7 lines 33-35). Moorehead et al. does not specifically disclose the

mounting portion to cover a minority of a surface area of the lumen occluding portion in which the slit is disposed. However, Ohringer teaches a slit diaphragm (Fig. 2 diaphragm 17) mounted between control plate 19 and flanges 13 and 15 and specifically teaches that by varying the diameter of the opening d3 in plate 19 surrounding the slit 31 you can control the flow through the slit. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to increase the size of the slit in Moorehead et al. in order to control the flow (Moorehead Col. 7 lines 22-25 and 30-35) and thereby increase the diameter of the mounting portion to accommodate the slit in the device in Moorehead et al. to further control the flow because Ohringer explicitly teaches that varying the diameter of an aperture around a slot is an art recognized means for flow control. Ultimately, as the diameter of the aperture surrounding the slit is varied in an increasing manner to accommodate the slit and control the flow this would cause the mounting portion to cover a minority of the surface area.

With regard to claims 2 and 4, Moorehead et al. teach a flow control membrane composed of a first membrane (Fig. 5 element 124), an annular base membrane (Fig. 5 element 120) wherein an area of the base membrane substantially corresponds to that of the mounting portion and wherein the slit extends through the first membrane (Fig.5). Moorehead et al. does not specifically teach bonding the first membrane to the annular base membrane, further, with regards to claim 4, Moorehead et al. does not teach adhesive bonding between membranes. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to adhesively bond an annular base (120) to a diaphragm (124) as such is an art recognized effective way of securing membrane layers together so as to maintain them in a desired position.

With regards to claim 3, Moorehead et al. teach a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 5 elements 90, 120, 124, Col. 6 lines 47-53). Additionally, the outer periphery of the membrane (Fig. 5 elements 120, 130) is contiguous with the housing (Fig. 5 element 90). Therefore, the housing is applying a compressive retentive force on the membrane, as the membrane is secured within the housing and not free to move.

10. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead et al. (U.S. Patent 5,205,834) in view of Ohringer (U.S. Patent 3,811,466) as applied to claims 1 and 2 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

With regard to claims 5 and 6, Moorhead et al. teach a pressure activated valve substantially as claimed. Moorehead et al. differs from claims 5 and 6 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col. 7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use membranes of a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.



With regard to claim 7, Moorhead et al. teach a pressure activated valve substantially as claimed. Moorehead et al. differs from claim 7 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the membrane portions (Fig. 5 elements 122, 124) in Moorehead et al. as applied to claims 5 and 6. It directly follows that the thickness of the mounting portion will be between 1 and 6 times the thickness of the lumen occluding portion.

***Response to Arguments***

11. Applicant's arguments filed June 23, 2008 in the Appeal brief have been fully considered but they are not persuasive. The Examiner has relied upon the teaching that the diameter d3 of the plate 19 surrounding the slit can be varied to control the flow (Col. 2 lines 50-51). The specific incorporation of lines 40-41 of Column 2 has been removed for clarification. Regardless, the Examiner did not use the teaching found at lines 40-41 of Column 2 to suggest the diameter of flange 13 be altered. The teaching regarding varying the diameter d3 in order to control the flow is applied to the reference in Moorehead et al. It is irrelevant whether or not it would have been obvious to vary the diameter d1, as found in the Applicant's arguments starting on page 5 line 9. The teaching of varying a diameter around a slit to control the flow remains valid and as such in the instance when increasing the diameter around the slit to control flow the corresponding mounting portion would cover a minority of the surface area of the lumen occluding portion in which the slit is disposed. Further, the rejection has been modified to

clarify the teaching in Moorehead et al. that slit and aperture size are variables which are set to determine the pressure differentials which cause the slit to be opened.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY WACHTEL whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Wachtel/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767